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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,559	12/17/2001	Klaus Kramer	52049	6211

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/015,559	Applicant(s) KRAMER ET AL	
	Examiner Russell Travers, J.D., Ph.D	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The amendment filed November 3, 2003 has been received and entered into the file.

Applicant's arguments filed November 3, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 3-9 and 11 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

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- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth those procedures effective in “protecting human skin or human hair against the aging process”. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these procedures without undue experimentation. In the instant case, applicants fail to provide even a limited number of procedure examples illustrated as effective in “protecting human skin or human hair against the aging process”, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of procedures required to practice the invention as claimed. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all procedures effective in “protecting human skin or human hair against the aging process”, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

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Claims 3-8 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 3-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-8 are rendered indefinite by the phrase "protecting human skin or human hair against the aging process" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining procedures effective in "protecting human skin or human hair against the aging process" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph. Examiner notes few procedures have been shown as effective in protecting against the aging process. Although many procedures have been illustrated as masking the appearance of the aging process, all efforts to protect against aging have been unsuccessful. Absent an amendment directing the claims to masking the aging process, or a showing illustrating suppression of the aging process, the skilled artisan would see the instant claims as properly rejected as indefinite under 35 USC 112, second paragraph.

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3-9 and 11 rejected under 35 U.S.C. § 103 as being unpatentable over Jiang et al in view of Burton et al.

Jiang et al teach various tocopherol compounds, to include gama-CEHC, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Burton et al teach various tocopherol compounds, to include alpha-CEHC esters, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These antioxidant medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as providing those benefits herein envisioned. Attention is directed to Jiang et al (page 11494, column 2, paragraph 2) teaching the antioxidant properties of gama-CEHC as the basis of the anti-inflammatory activity reported by Jiang et al. Examiner notes Burton et al teach

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alpha-CEHC compounds as old and well known antioxidant compounds possessing great antioxidant potential. Claims 3-9 and 11, and the primary reference, differ as to:

- 1) recitation of the envisioned use for the instant compositions, and
- 2) administration levels of the medicaments.

The skilled artisan, possessing a compound for an old and well known therapeutic use possesses that compounds isomers, analogs, homologs, bioisosteres for the same use. Attention is directed to *In re Ward* 141 USPQ 227 (CCPA 1964) and *Galaxo Operations U.K. Ltd. V. Quigg* 13 USPQ2d 1628, setting forth guidelines regarding therapeutic compounds relationships. Those compounds taught as obvious over the therapeutic compound are acids, ethers, esters and all salts. In the instant case, Applicants attempt to capture these obvious variants of the old and well known therapeutic compounds. Absent an illustration of unexpected benefits residing in the specific compounds herein claimed, the instant claims remain properly rejected under 35 USC 103. In the instant case, the teachings of Jiang et al, illustrating antioxidant benefits as the basis of the anti-inflammatory action, motivates the skilled artisan to employ closely related compounds to effect the desired therapeutic effect, absent information to the contrary. Burton et al teaches gama-CEHC as possessing great antioxidant activity, motivating the skilled artisan to employ such compounds for the use taught by Jiang et al.

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Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Absent information to the contrary, the skilled artisan would have seen the selection of one or another conventional therapeutic dosage as residing within the skilled artisan's purview. Attention is directed to Jiang et al (page 11495, column 2, paragraph 3) teaching administration levels far below those herein claimed as effective in providing anti-inflammatory activity.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new. Those utilities recited would be provided by those benefits recited in the Examiner cited prior art. Possessing the anti-oxidant use recited by Burton et al, the skilled artisan would be motivated to employ the claimed compounds for dermal use and enjoy a reasonable expectation of success. Thus, the skilled artisan would have seen the instant compositions of matter as obvious over the prior art of record.

RESPONSE TO ARGUMENTS

Newly presented rejections were necessitated by Applicants amendments.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.


Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617